

Claims:

✓ 1. A method of preparing a gene transcript pattern probe kit for diagnosing or identifying a disease or condition or stage thereof in a prokaryotic or eukaryotic organism comprising at least the steps of:

- a) isolating mRNA from the tissue, cells or body fluid of a normal prokaryotic or eukaryotic organism (normal sample);
- b) isolating mRNA from the corresponding tissue, cells or body fluid of an organism of step a) having the disease or condition of interest or a stage thereof (diseased sample);
- c) separating the mRNA of steps a) and b), which may optionally be reverse transcribed to cDNA, by a non-sequence based separation technique;
- d) selecting two or more mRNA or cDNA species which are present at different levels in the normal and diseased samples;
- e) isolating the mRNA or cDNA species identified in step d);
- f) optionally reverse transcribing the mRNA of step d) or e) to cDNA, unless this has previously been performed in step c); and
- g) immobilizing the mRNA or cDNA probes of step e) or f) on one or more solid supports.

2. A method as claimed in claim 1 wherein the mRNA of steps a) and b) is reverse transcribed to cDNA.

3. A method as claimed in claim 1 or 2 wherein said cDNA is amplified.

④ 4. A method as claimed in claim 2 or 3 wherein said cDNA produced from the mRNA of steps a) and b) incorporates a label.

5. A method as claimed in any one of claims 1 to 4 wherein between 50 and 100 mRNA or cDNA probes are isolated.

6. A method as claimed in any one of claims 1 to 5 wherein said separation technique is gel electrophoresis.

7. A gene transcript pattern probe kit for diagnosing or identifying or preparing a standard diagnostic gene transcript pattern of a disease or condition or stage thereof in a eukaryotic or prokaryotic organism comprising at least the following:

- a) one or more solid supports carrying two or more probe species as defined in any one of claims 1 to 5 corresponding to transcripts which reflect gene expression of one or more selected genes characteristic of the condition or disease or stage thereof in the organism under investigation.

8. A gene transcript pattern probe kit as claimed in claim 7 prepared according to any one of claims 1 to 6.

9. A kit as claimed in claim 7 or 8 additionally comprising mRNA or cDNA from normal and/or diseased samples, for comparative purposes.

10. Use of a kit as defined in any one of claims 7 to 9 for the preparation of a standard diagnostic gene transcript pattern.

11. A method of preparing a standard diagnostic gene transcript pattern characteristic of a disease or condition or stage thereof in a prokaryotic or eukaryotic organism comprising at least the steps of:

- a) isolating mRNA from the tissue, cells or body fluid of said organism having the disease or

- condition or stage thereof, which may optionally be reverse transcribed to cDNA,
- b) hybridizing the mRNA or cDNA of step a) to the mRNA or cDNA probes on a kit as defined in any one of claims 7 to 9 specific for said disease or condition or stage thereof in an organism corresponding to the organism under investigation; and
 - c) assessing the amount of mRNA or cDNA hybridizing to each of said probes on said solid support(s) to produce a characteristic pattern reflecting gene expression in the sample with the disease, condition or stage thereof of one or more selected genes corresponding to the probes.

12. A method as claimed in claim 11 wherein said mRNA of step b) is reverse transcribed to cDNA and optionally incorporates a label.

13. A method as claimed in claim 12 wherein said cDNA is amplified.

14. Use of a kit as defined in any one of claims 7 to 9 and/or use of a standard diagnostic gene transcript pattern prepared according to any one of claims 11 to 13 for the identification or diagnosis of said disease or condition or stage thereof in said organism.

15. A method of diagnosing or identifying a disease or condition or stage thereof in a prokaryotic or eukaryotic organism, comprising the steps of:

- a) isolating mRNA from the tissue, cells or body fluid of said organism, which may optionally be reverse transcribed to cDNA;
- b) hybridizing the mRNA or cDNA of step a) to a kit as defined in any one of claims 7 to 9

specific for said disease, or condition or stage thereof in an organism corresponding to the organism under investigation;

- c) assessing the amount of mRNA or cDNA hybridizing to each of said probes on said solid supports to produce a characteristic pattern reflecting gene expression of one or more selected genes corresponding to the probes;
- d) comparing said pattern to a standard diagnostic pattern prepared according to any one of claims 11 to 13 using a sample from an organism corresponding to the organism under investigation having said disease or condition or stage thereof under investigation to determine the degree of correlation indicative of the presence of said disease or condition or a stage thereof in the organism under investigation.

16. A method or kit as claimed in any one of claims 1 to 15 wherein said organism is human.

17. A method or kit as claimed in any one of claims 1 to 16 wherein said solid support is a filter.

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